



PUBLISHED IDENTAFI® CLINICAL STUDIES

StarDental® Instruments

GENDER MEDICINE, FEBRUARY 2012 SUPPLEMENT

Two studies were published in the peer reviewed journal Gender Medicine.

The two studies were conducted at the British Columbia Cancer Authority and led by Calum MacAulay, Department of Integrated Oncology at the British Columbia Cancer Research Centre and Michelle Follen, MD, a gynecologist and Vice Dean at Drexel University School of Medicine in Philadelphia and one of the original developers of the Identafi system.

These two articles are part of a series of studies and case reports which began in 2008 and are ongoing. The intention is to evaluate and support autofluorescence and narrow band reflectance (green amber light) in screening for oral cancer and its eventual use in detecting and treating cervical cancer.

The articles were published in a medical journal for that reason. The device referenced is the Trimira Identafi 3000 as these studies were undertaken in 2008 and 2009.

ON THE REVERSE SIDE IS A SUMMARY OF EACH ARTICLE

RT3-00371



ORAL FLUORESCENCE IMAGING USING 405-NM EXCITATION, AIDING THE DISCRIMINATION OF CANCERS AND PRECANCERS BY IDENTIFYING CHANGES IN COLLEGAN AND ELASTIC BREAKDOWN AND NEOVASCULARIZATION IN THE UNDERLYING STROMA.

This supports the original work done in the Roblyer study* in 2010 at Rice University which found that the 405nm wavelength unique to the Identafi device was best suited to identify precancerous and cancerous lesions. Nearly 120 patients participated in this study from which various types of lesions were identified through screening then photographed and confirmed with biopsies. Seventy-four of the lesions are presented in this paper demonstrating their appearance under white and violet (405nm) light. Note this study does not address the narrow band reflectance (green amber) of the Identafi system.

The conclusion: “Early results suggest that the addition of the fluorescence examination at 405nm is helpful in identifying characteristics indicative of precancer and cancer over that seen solely by comprehensive white light examination. Images in the violet induced autofluorescence at 405nm showed the deeper neovascularization of the stromal changes that accompanied the progression to neoplasia.”

Lane P, Lam S, Follen M, MacAulay C. Oral Fluorescence Imaging Using 405-nm Excitation, Aiding the Discrimination of Cancers and Precancers by Identifying Changes in Collegan and Elastic Breakdown and Neovascularization in the Underlying Stroma. *Gend Med.* 2012 Feb;9(1 Suppl); S78-S82. e8

HAS FLUORESCENCE COME OF AGE? A CASE SERIES OF ORAL PRECANCERS AND CANCERS USING WHITE LIGHT, FLUORESCENCE LIGHT AT 405NM AND REFLECTED LIGHT AT 545NM USING THE TRIMIRA IDENTAFI 3000.

This paper documents a series of case studies performed within three clinical environments using the Identafi system. Images using the three wavelength of light were used and the lesions photographed. Biopsies confirmed the diagnoses. This paper includes an image of the Identafi device and 12 different lesions.

The Conclusion...“Given that oral neoplasm is rare, the need for a device that increases the sensitivity of the comprehensive white light oral screening is evident. Such a device in the hands of dentist, family physicians, otorhinolaryngologists, general surgeons, obstetricians and gynecologists and internists, could greatly increase the number of patients who have lesions detected in the precancerous phase.”

Lane P, Follen M, MacAulay C. Has Fluorescence Come of Age? A Case Series of Oral Precancers and Cancers Using White Light, Fluorescence Light at 405nm and Reflected Light at 545nm using the Trimira Identafi 3000. *Gend Med.* 2012 Feb;9(1 Suppl); S25-35

*Roblyer D, Kurachi C, Stepanek V, Schwarz RA, Williams MD, El-Naggar AK, Lee JJ, Gillenwater AM, and Richards-Kortum R. Comparison of multispectral wide-field optical imaging modalities to maximize image contrast for objective discrimination of oral neoplasia. *Journal of Biomedical Optics*, Volume 15, Issue 6, 066017, Nov-Dec 2010